



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/765,086 | 01/17/2001 | Erkki I. Ruoslahti | P-LJ 4575 | 6131 |

23601 7590 09/12/2003
CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 09/12/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,086

Applicant(s)

RUOSLAHTI ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-17 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-17 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 05 June 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-5-2003 has been entered.

Claims 8-17, and 23-27 are pending and examined on merits.

Drawings

The drawings were received on June 01, 2003. These drawings are acceptable.

Response to Amendment

The Declaration filed on 6-5-2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Ellerby et al (1999) reference for following reasons:

The evidence submitted is insufficient to establish applicant's alleged actual reduction to practice of the invention in this country or a NAFTA or WTO member country after the effective date of the Ellerby et al (1999) reference. First, the declaration shows some evidence of conception or reduction to practice of only parts of the claimed subject matter. The Declaration does not disclose the structure of the chimeric peptide. However, the structure in the attached proposal (Exhibit 1) at page 3, left column, 2nd and 3rd paragraphs suggests that the chimeric peptide used in the Exhibit 1 appears to be SMSIARL-GG-(KLAKLAK)₂, not SMSIARL-GG-d(KLAKLAK)₂ as in instant claims 11, 12, 16, and 17. Second, the Declaration does not establish that

Art Unit: 1642

the concept or reduction to practice was by applicants (the inventive entity). The applicants for this case are Drs. Erkki Rouslahti, Renata Pasqualini, Wadih Arap, Dale Bredesen, H.Michale Ellerby. The Declaration states that "I" (the Office interprets "I" as Dr. Erkki Rouslahti since Dr. Erkki Rouslahti signed the Declaration) supervised construction of a chimeric peptide containing a prostate-homing peptide and an antimicrobial peptide, and that Wadih Arap submitted the CaP CURE proposal. This does not prove the inventive entity of the claimed subject matter by Erkki Rouslahti, Renata Pasqualini, Wadih Arap, Dale Bredesen, and H.Michale Ellerby before the publication. Note MPEP 715 for swearing behind a reference, especially 715.01, 715.01(c), 715.02 715.04 for who has to sign, and 715.07 what kinds of evidence has to be shown to correct the deficiency.

Claim Rejections - 35 USC § 103

Claims 8-17, and 23-27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/46284 (IDS, 1999) and Ellerby et al (IDS, September 1999, Nature Medicine 5, 1032-1038) in view of Arap et al (previously cited, 16 January 1998, Science Vol. 279, 377-380). This is substantially duplicate of the previous 35 U.S.C. 103(a) rejection but many of the references are dropped as art of record in view of applicant's argument and the rejection is slightly re-worded as follows:

The claims are interpreted as drawn to method of directing an antimicrobial peptide to non-cancerous, normal cells in prostate tissue using a prostate homing peptide for causing apoptosis of the targeted cells. WO 99/46284 teaches peptides capable of binding to the endothelial cells of prostate for example the peptide structure

Art Unit: 1642

shown in instant claim 24. WO 99/46284 does not teach an anti-microbial peptide. However, Ellerby et al teaches the antimicrobial peptide as shown in, for example instant claim 26, and the coupling domain of GG in Fig. 1 and further teach directing the antimicrobial peptide to angiogenic endothelial cells results in anti-cancer activity. Arap et al teaches why one of ordinary skill would direct some useful anti-cancer agents to non-cancerous cells of a tissue at the last paragraph, i.e. nonmalignant endothelial cells is more desirable target because they are less mutating. It is the Office's position that the ultimate goal for the instant invention is cancer treatment using the product(s) in the claims and one of ordinary skill in the art is motivated to find effective cancer treatment method. Removing Ellerby reference as prior art is desired, then applicant should correct the deficiencies of the Declaration as noted above.

Double Patenting

Applicant is advised that should claims 11,16, 25 be found allowable, claim 12, 17, 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.


Application/Control Number: 09/765,086
Art Unit: 1642

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
September 5, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
/b00